

July 17, 2019

Dear Requestor,

After a diligent search of our files, the Division of Import Operations (DIO) of the Office of Regulatory Affairs (ORA) of the Food and Drug Administration (FDA) was unable to locate any records responsive to your request 2018-6917 dated August 24, 2018 regarding:

TIANAPTINE RECS

Please be advised that your request may have been submitted to one or more component offices within FDA to conduct a search for records including the *Center for Drug Evaluation and Research*. These offices will reply to you directly. This is not the agency final response and you will receive additional appeal rights with the final response, so you do not have to act at this time.

You have the right to appeal this determination. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision. Your appeal must be mailed within 90 days from the date of this response, to:

Agency Chief FOIA Officer
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Public Affairs
Room 729H
200 Independence Avenue, S.W.
Washington, DC 20201
e-mail FOIARequest@PSC.hhs.gov.

Please clearly mark both the envelope and your letter or e-mail "FDA Freedom of Information Act Appeal.

If you would like to discuss our response <u>before</u> filing an appeal to attempt to resolve your dispute without going through the appeals process, please contact **person that worked on request**. You may also contact the FDA Public Liaison for assistance at

Office of the Executive Secretariat U.S. Food & Drug Administration 5630 Fishers Lane, Room 1050 Rockville, MD 20857

E-mail: FDAFOIA@fda.hhs.gov.



If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is as follows:

Office of Government Information Services National Archives and Records Administration 8601 Adelphi Road—OGIS College Park, MD 20740-6001 Telephone: 202-741-5770

Toll-Free: 1-877-684-6448 E-mail: ogis@nara.gov

Please do not submit payment until you receive an invoice. The following charges for this request to date may be included in a monthly invoice:

Reproduction=\$0.00 Search=\$23.00 Review \$0.00 Other \$0.00 Total=\$23.00

(Note: C and O type requestors are charged a \$5.75 administrative fee. This fee does not apply to N type requestors.)

Sincerely yours,

Ted Poplawski for John E. Verbeten Director, Division of Import Operations

JEV:smb

No Enclosures included

cc: HFS-170, File copy
DIO Correspondence File

U.S. Food and Drug Administration 12420 Parklawn Drive, ELEM-3109 Rockville, MD 20857 www.fda.gov